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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|----------------------------|----------------------|-------------------------|------------------|
| 10/566,078 | 01/30/2008 | Fernando Patolsky | 27209U | 9431 |
| ²⁰⁵²⁹ THE NATH L <i>A</i> | 7590 12/01/200 AW GROUP | EXAMINER | | |
| 112 South West Street | | | BHAT, NARAYAN KAMESHWAR | |
| Alexandria, VA 22314 | | | ART UNIT | PAPER NUMBER |
| | | | 1634 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 12/01/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|--|---|-----------------|--|--|--|--|
| Office Action Commons | 10/566,078 | PATOLSKY ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | NARAYAN K. BHAT | 1634 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>27 Ja</u> | nuary 2006 | | | | | |
| | | | | | | |
| · <u> </u> | <i>,</i> — | | | | | |
| | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 455 C.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-13,15,17-21,24,30 and 32-36</u> is/are pending in the application. | | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
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| | | | | | | |
| 7) Claim(s) is/are objected to. | ht4.4 | | | | | |
| 8)⊠ Claim(s) <u>1-13,15,17-21,24,30 and 32-36</u> are su | bject to restriction and/or election | n requirement. | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| ·— <u> </u> | a) All b) Some * c) None of: | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Da | te | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) 5) Notice of Informal Patent Application 6) Other: | | | | | | |
| Paper No(s)/Mail Date 6) Other: | | | | | | |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-13, 15 and 17-20 are drawn to a method for determining an analyte in an assayed sample.

Group II, claims 21, 24, 30 and 32-36 are drawn to a sensing device and a kit for determining analytes in the sample.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The claim 1 of the group I invention is drawn to a method for determining an analyte in an assayed sample, comprising: a) providing semiconductor nanoparticles carrying a recognition agent capable of specifically binding to the analyte, b) contacting semiconductor nanoparticles with the assayed sample; c) providing an acceptor capable of immobilization directly or indirectly, in the presence of the analyte, to the recognition agent; d) providing assay conditions for the direct or indirect immobilization of the acceptor to the recognition agent in the presence of the analyte, (e) irradiating the semiconductor nanoparticles and transfer energy to the acceptor; and generation of an

electromagnetic signal and detecting the signal as indicative of the presence and/or the amount of said analyte in the sample.

Clams 21, 24, 30 and 32-36 of the group II invention are drawn to a sensing device and a kit for determining two or more analytes in an assayed sample, the device comprising assay unit comprising a system of semiconductor nanoparticles carrying recognition agents and acceptor capable of immobilization, in the presence of the analyte and under assay conditions, to the recognition agent.

The common technical feature as defined by group II, linking group I is the system of semiconductor nanoparticles carrying recognition agents and acceptor capable of immobilization, in the presence of the analyte and under assay conditions, to the recognition agent. However, the structural features of the system of semiconductor nanoparticles carrying recognition agents and acceptor are taught by Bruchez et al (USPGPUB 2002/0039732 published Apr. 4, 2002).

Bruchez et al teaches a system comprising semiconductor nanoparticles (i.e., SCNC, paragraph 0059) carrying looped probe capable of recognizing a target analyte (Fig. 5, SCNC looped probe -panel 1 from the left side, target analyte -panel 4 from the left side and paragraph 0023) and acceptor (i.e., encoded microsphere coated with SCNC-Streptavidin, Fig. 5, Acceptor-panel 2 from the left side) capable of immobilization in the presence of the analyte and under assay conditions to the SCNC particle carrying the recognition agent (Fig. 5, panel 5 from the left side and paragraph

0023). Bruchez also teaches sensing device for determining the presence of plurality of different analytes (paragraph 0016).

Since Bruchez et al teaches the recited structural features of the system of semiconductor nanoparticles and acceptor of the instant invention, the technical feature linking groups I and II does not constitute a special technical feature as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. Thus, there is no special technical feature linking the recited groups, as would be necessary to fulfill the requirements for unity of invention.

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

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§ 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of invention to be examined even though the requirement is traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Narayan K. Bhat

Examiner, Art Unit 1634

/BJ Forman/

Primary Examiner, Art Unit 1634